



5. 510(k) SUMMARY

Submitter: MedCAD
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Date Prepared: March 09, 2011

Trade Name: MedCAD AccuShape™ PEEK Patient Specific Cranial Implant (PSCI)

Common Name: Patient Specific Cranial Implant (PSCI)

Classification Name: Preformed nonalterable cranioplasty plate

Product Code: GXN

Classification: Class II, 21 CFR 882.5330

Predicate Device: K033868 – Synthes Patient Specific Cranial/Craniofacial Implants
K072601 – OsteoSymbionics Patient-Specific Cranial Implant

Device Description: The MedCAD AccuShape™ PEEK Patient Specific Cranial Implant devices are individually sized and shaped implantable prosthetic cranioplasty plates intended to correct defects / replace voids in the cranial skeleton of a specific patient. The implants are designed using the patient's CT imaging data and precision manufactured from implantable grade polyether-ether-ketone (PEEK) material.
The devices have a nominal thickness of 3mm, ranging from 2-5mm depending on the anatomical location. The device can be supplied as one or as multiple parts due to material constraints and/or the complexity of the device, with each part ranging in size from 10 x 10 (mm) to 200 x 200 (mm). The implants are provided with 2mm drainage holes spaced 10 mm apart from center to center with an edge margin of 10 mm.
The devices are non-pyrogenic and are provided non-sterile for sterilization by the physician prior to implantation. The implants are attached to the native bone with commercially available cranioplasty fasteners.

Statement of Intended Use: The MedCAD AccuShape™ PEEK Patient Specific Cranial Implant is designed individually for each patient and intended to correct defects / replace bony voids in the cranial skeleton.



**Summary of
Technological
Characteristics:**

The MedCAD AccuShape™ PEEK Patient Specific Cranial Implant device is substantially equivalent to the predicate devices regarding use of electronic CT images and computer aided design in determining patient specific implant dimensions, use of implantable grade polymer as the device material, and resulting technological characteristics including biocompatibility, sterilization method, strength, stiffness, elasticity, density, and radiolucency.

**Summary of
Non-Clinical Test
Data:**

Biological laboratory tests including thorough sterilization validation have been conducted for the MedCAD Patient Specific Cranial Implant devices and material. These tests have proven the devices to be pyrogen-free and sterile, when used in accordance with the product instructions. Precision measurements have validated the dimensional accuracy and stability of the devices. In addition, material testing has been performed to demonstrate structural integrity. Together, these non-clinical tests assure that the MedCAD AccuShape™ PEEK Patient Specific Cranial Implant safety and effectiveness are substantially equivalent to those of the predicate devices.

Conclusion:

MedCAD considers the MedCAD AccuShape™ PEEK Patient Specific Cranial Implant to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, materials, test results, and established medical use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

VanDuzen dba MedCAD
c/o Ms. Diane Rutherford
Regulatory Engineer
Ken Block Consulting
1201 Richardson, Suite 280
Richardson, TX 75080

JUN 24 2011

Re: K110684

Trade/Device Name: MedCAD AccuShape™ PEEK Patient Specific Cranial Implant
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed nonalterable cranioplasty plate
Regulatory Class: Class II
Product Code: GXN
Dated: May 31, 2011
Received: June 01, 2011

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

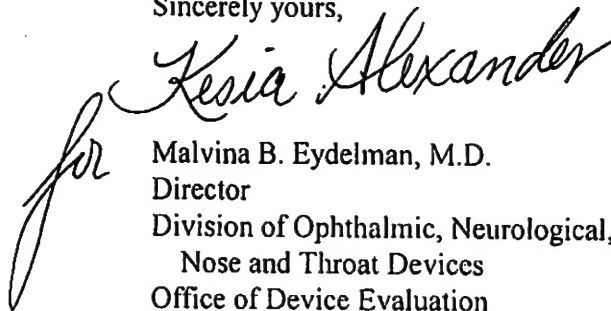
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Kesia Alexander". To the left of the signature, the word "for" is written in a cursive script.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K110684


Device Name: MedCAD AccuShape™ PEEK Patient Specific Cranial Implant

Indications for Use:

The MedCAD AccuShape™ PEEK Patient Specific Cranial Implant is designed individually for each patient and intended to correct defects / replace bony voids in the cranial skeleton.

Prescription Use X
(21 CFR 801 Subpart D)AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices510(k) Number K110684